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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,932	07/21/2006	Else Marie Celine Defoor	10556.204-US	1922

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
08/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,932	DEFOOR ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-41,43-56,58,60-80 and 82* is/are pending in the application.

4a) Of the above claim(s) *61-80 and 82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-41,43-56,58 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-3-09 has been entered.

Claims 37-41, 43-56, 58, 60-80 and 82 are pending.

Claims 61-80 and 82 are withdrawn from consideration. Claims 37-41, 43-56, 58 and 60 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-41, 43-56, 58 and 60 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons made of record in the Office Actions mailed 4-18-08 and 12-15-08.

Applicant's arguments have been carefully considered but are not persuasive. Applicants argue that the specification is enabled and as such the written description rejection is inappropriate because more is not required. This is not persuasive because the statute requires (i) a written description of the invention and (ii) the manner and process of making and using it. There are clearly two requirements are distinct and the judicial precedent set forth by the courts have indicated that the issues are severable.

The fact based inquiry for written description is essentially a question of whether or not the specification contains a written description sufficient to show that Applicants had possession of the full scope of their claimed invention at the time the application was filed as required by Federal Circuit precedent. The following finding of facts are noted for the record. The claims are drawn to recombinant marker genes and polynucleotide constructs encoding orotate transporter polypeptides are 95%, 96%, 97% or 99% identical to SEQ ID NO:2. The specification discloses SEQ ID NO:2 (an orotate transporter polypeptide) encoded by the nucleic acid of SEQ ID NO:1. The specification does not disclose any variants in which the polypeptide of SEQ IDNO:2 is varied and has the function of orotate transport as claimed. The specification does not disclose which amino acid residues could be changed in order to maintain the biological function of orotate transport. The specification discloses and Applicants describe and characterize ysbC the specification at page 1, "A search in the public databases for any polypeptide having amino acid homology to the orotate transporter of the present invention, revealed that the closest polypeptide had less than 35% sequence identity, and it was completely unrelated to the orotate transporter of the present invention. Consequently, the ysbC-encoded orotate transporter represents **a completely pioneering new class of molecules** [emphasis added]." The prior art and the skilled artisan therefore does not recognize a correlation of the structure of the orotate trasporter polypeptide with the function of "orotate transport" based on similarities to other orotate transporters or proteins of the prior art.

The specification does not disclose a correlation between function of orotate transport and the structure of SEQ ID NO:2 responsible for this function such that the skilled artisan would have known what modifications could be made without losing the function of orotate transport.

In spite of concluding that the claims are enabled, Federal Circuit caselaw compels the finding that the written description requirement is not met. Although there is often "significant overlap" between the enablement and written description requirements, "they are nonetheless independent of each other." *University of Rochester*, 358 F.3d at 921, 69 USPQ2d at 1891. An "invention may be enabled even though it has not been described." *Id.* Such is the situation here. While one skilled in the art would have been able to make and use the full scope of the claims through routine experimentation, Applicants have not described the invention of the claims sufficiently to show they had possession of the claimed genus of nucleic acids/constructs as claimed. *See, e.g., Noelle v. Lederman*, 355 F.3d 1343, 1348, 69 USPQ2d 1508, 1513 (Fed. Cir. 2004) ("invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*").

The claims are drawn to a genus of genes or polynucleotide constructs encoding polypeptides "at least 95% identical to SEQ ID NO:2" which encode an orotate transporter polypeptide. Sufficient description to show possession of such a genus "may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

In this case, Applicants have sequenced one nucleic acid falling within the scope of the claims and thus the single sequence is not representative of the genus of variants.

Applicants also have described how to make and test other sequences within claim sufficiently to satisfy the enablement requirement. However, Applicants have not described what domains of those sequences are correlated with the required orotate transport functions, and thus have not described which of the amino acids can be varied and still maintain transport. Thus, under *Lilly* and its progeny, the Specification does not show possession of a sufficient number of sequences falling within the potentially large genus to establish possession of the claimed genus. *Cf. Enzo*, 323 F.3d at 964, 63 USPQ2d at 1612 ("if the functional characteristic of . . . orotate transport were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed," the written description requirement may be met).

Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 ("definition by function … does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is").

With respect to Applicants' reliance on hypothetical Examples in the Office's Guidelines, "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (quoting *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971)), *quoted with approval in Enzo*, 323 F.3d at 963, 63 USPQ2d at 1612. While the *Written Description Guidelines* and the hypothetical examples in the Office's *Synopsis* can be helpful in understanding how to apply the relevant law, they do not create a rigid test.

The rejection is maintained for reasons made of record and arguments that the specification is enabled are not persuasive.

Claims 37-41, 43-56, 58 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the product of a recombinant marker gene or polynucleotide construct. However, the claims recite the gene or construct "disposed" in a cell. It is completely unclear if Applicant's are intending to claim the product of a gene or polynucleotide construct (nucleic acid molecule) or a living cell. These products have different structures as evidenced by the lack of unity between them set forth in the final rejection of 12-15-08. As such, it is completely unclear what product *per se* is being claimed. Further, it is noted that Applicants have received an action on the merits for the elected invention of a nucleic acid. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. The cell products are withdrawn from consideration on this record and the claims have been interpreted for purposes of this office action as being drawn to the nucleic acid molecules *per se* and not cells per se.

As to claims 41 and 50, the claims recite a process limitation and it is unclear how this limits the structure of the recombinant maker gene. Applicant's should clearly amend the claims to provide for a structure that limits the gene structure as claimed in claim 37. For example "The recombinant maker gene of claim 37, wherein the gene further comprises at least one heterologous and/or artificial promoter."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-41, 43-56, 58 and 60 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bolotine et al (FR 2807446, published October 10, 2001; pages 1-87, 120, 183, and 198-217 only) for reasons made of record in the Office Action mailed 4-18-08 and 12-15-08.

Bolotine et al teach the entire genome sequence of *Lactococcus lactis*. Bolotine et al also teach the polypeptide open reading frames and corresponding nucleic acids (see Tables 1 and 2. In particular Bolotoine et al teach open reading frame 1806 entitled ysbC at page 183 and it corresponding encoding nucleotide sequence at page 120. The polypeptide sequence is 98.5% identical as compared with the nucleic acid set forth in SEQ ID NO:2 (see attached alignments). The sequence of the prior art is also 100% identical with "an amino acid sequence identical to SEQ ID NO:2", as "an amino acid sequence" in the claims has been interpreted as reading on any subsequence or fragment of SEQ ID NO:2. Bolotine et al teach the nucleic acid comprising a heterologous promoter in conventional plasmids or integrative vectors for the expression of the encoded polypeptide and are contained in a host cell (see the disclosure pages 1-86 and claims 1-110 in particular). The claimed functions are inherent to the nucleic acid and polypeptide structure(s). As such, the structure necessarily has the claimed function(s) in the absence of convincing factual evidence to the contrary. Since the Office does not have the facilities for examining and comparing applicant's nucleic acid and protein with the nucleic acid and protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art polypeptide and nucleic acids do not possess the same functional characteristics of the claimed nucleic acid encoding the protein). See *In re*

Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Applicant's amendments do not obviate the rejection of record. Disposed in a pyrimidine auxotrophic cell does not structurally define the recombinant maker gene/construct over the prior art. The claims have been interpreted as drawn to the product of a recombinant maker gene or polynucleotide construct *per se* and not a cell. Applicant has not addressed the interpretation of the claims with respect to the "an amino acid sequence" reading on a fragment that is 100% identical. Applicants argue that the gene is not in a pyrimidine auxotrophic cell. This is not persuasive because the presence in a host cell or in a pyrimidine oxotrophic cell does not distinguish the structure of the claimed nucleic acid molecule. Applicant's claims are drawn to nucleic acid molecules and constructs, not cells *per se*.

Furthermore, the recombinant gene sequence that is 98.5% identical as compared to SEQ ID NO:2 and 100% identical to a fragment of SEQ ID NO:2 is contemplated with a heterologous promoter, in a plasmid or integrative vector and contain in host cells.

Status of the Claims

Claims 37-41, 42-56, 58 and 60 stand rejected. All other claims are withdrawn from consideration.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner